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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/585,925	06/02/2000	Paul Rafferty	2079.1024008	6299

7590 05/21/2003  
Giulio A. DeConti, Jr.  
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Boston, MA 02109

EXAMINER

LIU, HONG

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 05/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/585,925

Applicant(s)

RAFFERTY ET AL.

Examin r

Hong Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 April 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-26 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37 and 38 is/are allowed.
- 6) ☒ Claim(s) 16-26 and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Claims 16-26, and 36-38 are pending in this application.

This action is in response to the applicants' amendment and reply filed on April 2, 2003.

### **Response to Arguments**

Applicants' arguments filed on April 2, 2003 have been fully considered but they are not persuasive. Rejections to Claims under 35 U.S.C. 112, first and second paragraph are maintained.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

Claims 16-26 and 36 remain rejected under 35 U.S.C. 112, first paragraph, for reasons already made of record notwithstanding applicants' traverse. Applicants argue that the application as originally filed provided adequate written description requirement and the proviso inserted by applicants to overcome the prior art merely excises a small group of compounds. Following the logic of applicants' argument, the amended claim can be viewed to consist of a genus as originally filed and a sub-genus created by the proviso in response to the art rejection. The issue then is whether one ordinarily skilled in the art can foresee that the species can be excluded when he or she reads the original claim. Whether the general mentioning of the subject matter, i.e., generic description, can be viewed to provide support for a later claimed species depends on the embodiments specifically disclosed in the specification. The issue was very well

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addressed in *Ruschig*. *Ruschig* is a chemical case with 12 original claims.<sup>1</sup> About a year after the application was filed, the examiner suggested that claim 13, the claim corresponding to the interference count, be added for purpose of interference with a Pfizer application. Claim 13 is drawn to a specific compound, N-(p-chlorobenzenesulfonyl)-N'-propylurea, which falls within the genus disclosed in the original patent application. Pfizer argued that the interference should be dissolved because the claim was not supported in the original disclosure. The court agreed with Pfizer reasoning that the generic description in the original disclosure contained half a million possible compounds. Although the applicants disclosed a number of specific compounds, one skilled in the art would not "find certain 'guides' in the specification which would lead him to the compound of claim 13."<sup>2</sup> The court stated,

It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail...to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.<sup>3</sup>

The blaze mark test suggests that in order for one skilled in the art to be aware of the excluded sub-genus, applicants have to provide the blaze marks or guidance to lead the one skilled in the art to the sub-genus. Here, the exclusion of the compounds occurs only after the prior art has been found. Therefore, there is no way for one skilled in the art to know that these compounds will be excluded. there is no blaze marks that could lead one of skill in the art to the compounds with the special relationship between R, R14 and R15. Such an amendment is quite similar to the amendment in an interference in which applicants have a generic description of the

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<sup>1</sup> *In re Ruschig, Aumuller, Korger, Wagner, Scholz and Bander*, 379 F2d 990, 154 U.S.P.Q. 118 (C.C.P.A. 1967).

<sup>2</sup> *Id.* 154 U.S.P.Q. 118 at 121.

<sup>3</sup> *Id.* 154 U.S.P.Q. 118 at 122.

compounds and later try to add a species that falls within the genus.<sup>4</sup> The difference is that in the *Ruschig* situation, applicants try to add a species falling within the genus and in the example, applicants try to remove some species or a subgenus from a genus. What is not permissible in *Ruschig* should not become permissible here.

Even if we assume that applicants did have the possession of the invention, the criterion of possession alone is insufficient to determine whether the application has met the written description requirement. In *Enzo Biochem*,<sup>5</sup> the court clarified this issue by stating that possession alone was not always sufficient to meet the written requirement. A showing of “possession” is ancillary to the statutory mandate that “the specification shall contain a written description of the invention.”<sup>6</sup> The written description requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention. The court concluded that a showing of possession alone did not cure the lack of a written description in the specification required by statute.

Rejections 1) and 4) to claims 16-26 under 35 U.S.C. 112, second paragraph, is maintained for reasons already made of record. As stated, the term “a suitable substituent” does not specify the nature of the substitution. Applicants argue that these terms are defined in the specification and thus are definite and enabled when they are read in light of the specification. However, reading a claim in light of the specification is quite different from reading limitations of the specification into the claim. See *In re Prater*, 415 F.2d 1393, 162 USPQ 541. These claims themselves do not carry the limitation as specified in the specification. When the claims

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<sup>4</sup> *Fujikawa v. Wattanasin*, 93 F.3d 1559, 39 U.S.P.Q.2d 1895 (Fed. Cir. 1996).

<sup>5</sup> *Enzo Biochem Inc. v. Gen-Probe Inc.*, 296 F.3d at 1324, 63 U.S.P.Q.2d 1609. (Fed. Cir. 2002).

<sup>6</sup> *Id.* 63 U.S.P.Q.2d at 1617.

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having these phrases are given the broadest interpretation, it is still open-ended in terms of the array of heteroatoms, size of the rings, as well as nature of atoms as ring members.

***Conclusion***

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The fax phone number for this group is (703) 308-4734 for "unofficial" purposes and the actual number for official business is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

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May 20, 2003



Mukund Shah  
Supervisory Patent Examiner  
Art Unit 1624